



Package insert for the AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/MDMA/K2 test for oral fluids. A rapid, screening test for the simultaneous qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiate, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates, Buprenorphine, Cotinine, Methyleneiodoxymethamphetamine, Synthetic Cannabinoid, and their metabolites in human oral fluid.

For Forensic Use, or For Employment Use and Insurance Testing Use Only

INTENDED USE

The **Oral Cube® Oral Fluid Drug Screen Device** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/MDMA/K2 is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiate, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates, Buprenorphine, Cotinine, Methyleneiodoxymethamphetamine, Synthetic Cannabinoid, and their metabolites in oral fluids at the following cutoff concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	50 ng/mL
Methamphetamine (mAMP)	D-Methamphetamine	50 ng/mL
Cocaine (COC)	Benzoyllecgonine	20 ng/mL
	Benzoyllecgonine	50 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
	Morphine	50 ng/mL
Marijuana (THC)	Δ ⁹ -THC	25 ng/mL
	Δ ⁸ -THC	40 ng/mL
	Δ ¹⁰ -THC	50 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL
	Oxazepam	30 ng/mL
Benzodiazepines (BZO)	Oxazepam	50 ng/mL
	Oxycodone	50 ng/mL
Methadone (MTD)	Methadone	75 ng/mL
Barbiturates (BAR)	Butalbital	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cotinine (COT)	Cotinine	30 ng/mL
Methyleneiodoxymethamphetamine (MDMA)	(±)-3,4-Methyleneiodoxymethamphetamine	50 ng/mL
Synthetic Cannabinoid (K2)	JWH-018 Pentanoic Acid	20 ng/mL
	JWH-073 Butanoic Acid	
	JWH-018 Pentanoic Acid	
	JWH-073 Butanoic Acid	10 ng/mL

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) and gas chromatography/tandem mass spectrometry (GC/MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

This test is limited for forensic use, or employment use and insurance testing. This test system shall not be used for Federal drug testing programs.

SUMMARY AND EXPLANATION OF THE TEST

The **Oral Cube® Oral Fluid Drug Screen Device** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/MDMA/K2 and their metabolites is a rapid, oral fluid screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human oral fluid.

AMPHETAMINE (AMP)

Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion. Depending on the route of administration, Amphetamine can be detected in oral fluid as early as 5-10 minutes and up to 72 hours after use¹.

The Amphetamine assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Amphetamine concentration in oral fluid exceeds 50 ng/mL.

METHAMPHETAMINE (mAMP)

Methamphetamine is a potent stimulant chemically related to Amphetamine but with greater CNS stimulation properties. The drug is often self-administered by nasal inhalation, smoking, or oral ingestion. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes and up to 72 hours after use¹.

The Methamphetamine assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Methamphetamine concentration in oral fluid exceeds 50 ng/mL.

COCAINE (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (erythroxylum coca). The drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Depending on the route of administration, cocaine and metabolites benzoyllecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use¹. Cocaine and benzoyllecgonine can be detected in oral fluids for up to 24 hours after use¹.

The Cocaine assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Benzoyllecgonine concentration in oral fluid exceeds 20 ng/mL.

The Cocaine assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Benzoyllecgonine concentration in oral fluid exceeds 50 ng/mL.

OPIATE (OPI)

The drug class opiates refer to any drug that is derived from the opium poppy, including naturally occurring compounds such as Morphine, Codeine, and semi-synthetic drugs such as Heroin. Opiates act to control pain by depressing the central nervous system. Such drugs demonstrate addictive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take them intravenously or by nasal inhalation. Using an immunoassay cut-off level of 40 ng/mL, Codeine can be detected in oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose². 6-monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a metabolic product of Heroin. Morphine is the major metabolic product of Codeine and Heroin, and is detectable for 24-48 hours after an opiate dose.

The Opiate assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Morphine concentration in oral fluid exceeds 40 ng/mL.

The Opiate assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Morphine concentration in oral fluid exceeds 50 ng/mL.

MARIJUANA (THC)

Tetrahydrocannabinol, the active ingredient in the marijuana plant (cannabis sativa), is detectable in saliva shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity³. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use³.

The Marijuana assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Δ⁹-THC concentration in oral fluid exceeds 25 ng/mL.

The Marijuana assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Δ⁸-THC concentration in oral fluid exceeds 40 ng/mL.

The Marijuana assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Δ¹⁰-THC concentration in oral fluid exceeds 50 ng/mL.

PHENCYCLIDINE (PCP)

Phencyclidine, the hallucinogen commonly referred to as Angel Dust, can be detected in saliva as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and saliva sample collection of 100 patients in an Emergency Department, PCP was detected in the saliva of 79 patients at levels as low as 2 ng/mL and as high as 600 ng/mL⁴.

The Phencyclidine assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Phencyclidine concentration in oral fluid exceeds 10 ng/mL.

BENZODIAZEPINES (BZO)

Benzodiazepines are frequently prescribed as a sedative and hypnotic drugs for the symptomatic treatment of anxiety, insomnia, sleep and seizure disorders. Most Benzodiazepines are extensively metabolized in the liver and excreted in the urine and saliva as metabolites. Chronic abuse may increase the risk of physical dependence and may result in intoxication, drowsiness and muscle relaxation. Oxazepam is the major metabolic product of Benzodiazepines.

The Benzodiazepines assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Oxazepam concentration in oral fluids exceeds 30 ng/mL.

The Benzodiazepines assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Oxazepam concentration in oral fluids exceeds 50 ng/mL.

OXYCODONE (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to Codeine. The drug is manufactured by modifying Thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of Oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form.

The Oxycodone assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Oxycodone concentration in oral fluid exceeds 50 ng/mL.

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (Heroin, Vicodin, Percocet, Morphine). The pharmacology of oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like Heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone. Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal Heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by Heroin cessation, yet the substitution and phased removal of Methadone is an acceptable method of detoxification for patients and therapists⁵.

The Methadone assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Methadone concentration in oral fluids exceeds 75 ng/mL.

BARBITURATES (BAR)

Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of Barbiturates leads to tolerance and physical dependence. Short-acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

The approximate detection time limits for Barbiturates are:
Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days
Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days⁶

The Barbiturates assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Butalbital concentration in oral fluid exceeds 300 ng/mL.

BUPRENORPHINE (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

The Buprenorphine assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Buprenorphine concentration in oral fluid exceeds 10 ng/mL.

COTININE (COT)

Cotinine ((5S)-1-methyl-5-(3-pyridyl)pyrrolidin-2-one) is a first-stage metabolite of nicotine, an alkaloid that stimulates the autonomic ganglia and central nervous system in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. Aside from tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches, and nasal sprays. Once converted from Nicotine, Cotinine has an in vivo half-life in a human body for approximately 20 hours and is typically detectable for several days and up to one week after the use of tobacco. The level of cotinine in the blood, urine or saliva is proportionate to the amount of exposure to tobacco smoke. Cotinine, therefore, is a valuable indicator of tobacco smoke exposure, including secondary or passive smoke. People who smoke menthol cigarettes may retain cotinine in the blood for a longer period because menthol can compete with enzymatic metabolism of cotinine⁶. Genetic encoding of liver enzymes may also play a role, as people of African descent routinely register higher blood cotinine levels than Caucasians.⁷ Cotinine levels <10 ng/mL are considered to be consistent with no active smoking. Values of 10 ng/mL to 100 ng/mL are associated with light smoking or moderate passive exposure, and levels above 300 ng/mL are seen in heavy smokers who smoke more than 20 cigarettes a day. Values between 11 ng/mL and 30 ng/mL may be associated with light smoking or passive exposure, and levels in active smokers typically reach 500 ng/mL or more. Cotinine assays provide an objective quantitative measure that is more reliable than smoking histories. Cotinine also permits the measurement of exposure to second-hand smoke or passive smoking. Various types of drug tests can detect cotinine in the blood, urine, or saliva. Cotinine levels in saliva have been found to be the best marker for smoking status compared with saliva nicotine measurements, breath carbon monoxide testing, and plasma thiocyanate testing⁸.

The Cotinine assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Cotinine concentration in oral fluid exceeds 30 ng/mL.

METHYLENEDIKIOXYMETHAMPHETAMINE (MDMA)

Methyleneiodoxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of

increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via the release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlander, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The Methylenedioxymethamphetamine assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the Methylenedioxymethamphetamine concentration in oral fluid exceeds 50 ng/mL.

SYNTHETIC CANNABINOID (K2)

Synthetic Cannabinoid is a hallucinogen found as a mixture of herbs and spices that is typically sprayed with a synthetic compound chemically similar to THC, the psychoactive ingredient in marijuana. Since 2004, it has been sold in Switzerland, Austria, Germany and other European countries via internet shops without age restriction, attracting younger people. It is typically sold in small bags of dried leaves, resembling potpourri, and smoked in joints or pipes. Its psychological effects are similar to those of marijuana and include paranoia, panic attacks and giddiness. K2 can also cause an increased heart rate and increase of blood pressure. It appears to be stored in the body for long periods of time and the long-term effects on humans are not fully known.

The Synthetic Cannabinoid assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the concentration of JWH-018 Pentanoic Acid and JWH-073 Butanoic Acid in oral fluid exceeds 20 ng/mL.

The Synthetic Cannabinoid assay contained within the **Oral Cube® Oral Fluid Drug Screen Device** yields a positive result when the concentration of JWH-018 Pentanoic Acid and JWH-073 Butanoic Acid in oral fluid exceeds 10 ng/mL.

PRINCIPLE

The **Oral Cube® Oral Fluid Drug Screen Device** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/MDMA/K2 is an immunoassay based on the principle of competitive binding. Drugs that be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENT

The test contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Methamphetamine, Benzoylcegonine, Morphine, Marijuana, Phencyclidine, Oxazepam, Oxycodone, Methadone, Butalbital, Cotinine, Buprenorphine, Methylenedioxymethamphetamine and Synthetic Cannabinoid.

PRECAUTIONS

- For forensic use, or for employment use and insurance testing use only.
- Do not use after the expiration date.
- The oral fluid drug screen device should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The test device is for single use.
- The used collector and device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collector provided with the kit. Follow the detailed Directions for Use below. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

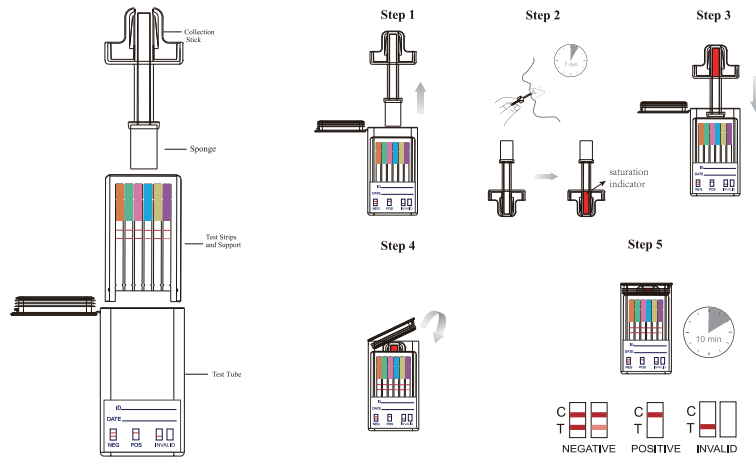
MATERIALS

Materials Provided
 • Test devices • Package insert • Procedure card
 Materials Required But Not Provided
 • Timer

DIRECTIONS FOR USE

Allow the test device to reach room temperature [15-30°C (59-86°F)] prior to testing. Do not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection of oral fluid specimen.

- Remove the collection stick and test tube from the sealed pouch.
- Tear off the package of the collection stick. (Step 1)
- Insert the sponge end of the collection stick into mouth and soak sponge into saliva, color on the saturation indicator will change to red. If at 7 minutes, color on the saturation indicator has not appeared, proceed with the step3.(Note: Time should be longer for people of little saliva. If the amount of saliva pressed into the test tube is not adequate for testing, collect more with another new collection stick and express the saliva into tube again.)(Step2)
- Hold the test tube vertically and place the collection stick with saturated sponge into the test tube. Make sure to fit the groove of collection stick onto the guide rail of test tube and press the collection stick to full extent. (Step 3)
- Press down the lid to close the test tube. Keep the test tube vertically until you begin to read the test results. (Step 4)
- Read results of drug tests at 10 minutes. (If there is a label over reading window, peel off the label to read test results.) **Do not read drug tests results after 15 minutes.** (Step 5)
- Send the collector with collected oral fluid to the laboratory for GC/MS confirmation if necessary.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE:

Two lines appear. * One color line should be in the control region (C), and another apparent color line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level. *NOTE: The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint distinguishable color line.

POSITIVE:

One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

INVALID:

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your supplier.

QUALITY CONTROL

A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

- The **Oral Cube® Oral Fluid Drug Screen Device** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) or gas chromatography/tandem mass spectrometry (GC/MS/MS) are the preferred confirmatory methods.
- A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
- A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cut-off level of the assay.
- The test has been developed for testing saliva samples only. No other fluids have been evaluated. Do NOT use this device to test anything but saliva.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and tested with the **Oral Cube® Oral Fluid Drug Screen Device**. The results are summarized below.

Drug Concentration Cut-off Range	n	AMP		mAMP		PCP		COC 20		COC 50		OPI40		OPI 50		THC 25		THC 40		THC 50				
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+			
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	
-25% Cut-off	30	28	2	29	1	30	0	30	0	30	0	27	3	28	2	29	1	27	3	29	1	30	0	
Cut-off	30	13	17	16	14	20	10	19	11	20	10	18	12	15	15	19	11	14	16	18	12	30	0	
+25% Cut-off	30	4	26	7	23	7	23	5	25	2	28	3	27	2	28	1	29	1	29	0	30	0	30	
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0

Drug Concentration Cut-off Range	n	BZO 30		BZO 50		BUP		OXY		MTD		BAR		COT		K2 20		K2 10		MDMA			
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+		
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	29	1	28	2	27	3	28	2	29	1	29	1	29	1	29	1	29	1	29	1	29	1
Cut-off	30	12	18	13	17	16	14	12	18	10	20	12	18	20	10	21	9	20	10	5	25	30	0
+25% Cut-off	30	2	28	4	26	7	23	3	27	2	28	3	27	2	23	7	23	7	10	0	30	0	30
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	10	0	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the **Oral Cube® Oral Fluid Drug Screen Device** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/MDMA/K2 identified positive results at a read time of 10 minutes.

Drug	Concentration (ng/mL)
AMPHETAMINE (AMP)	
D-Amphetamine	50
DL-Amphetamine	125
β-Phenylethylamine	4,000
(+)-3,4-Methylenedioxymphetamine (MDA)	150
L-Amphetamine	4,000
p-Hydroxyamphetamine	800
Tryptamine	1,500
Tyramine	1,000
METHAMPHETAMINE (mAMP)	
D-Methamphetamine	50
(1R,2S)-(-)-Ephedrine	400
Fenfluramine	60,000
Methoxyphenamine	25,000
3,4-Methylenedioxymphetamine	50
p-Hydroxymphetamine	400
L-Phenylephrine	4,000
Procaine	2,000
COCAINE (COC 20)	
Benzoylcegonine	20
Cocaine HCl	20
Cocaeethylene	25
Ecgonine HCl	1,500
Ecgonine Methyl Ester	12,500

COCAINE (COC 50)	
Benzoyllecgonine	50
Cocaine HCl	20
Cocaethylene	25
Ecgonine HCl	1,500
Ecgonine Methyl Ester	12,500
OPIATE (OPI 40)	
Morphine	40
Bilirubin	3,500
Codeine	10
Diacetylmorphine (Heroin)	50
Ethylmorphine	24
Hydrocodone	100
Hydromorphone	100
Levorphanol	400
6-Monoacetylmorphine	25
Morphine 3-β-D-Glucuronide	50
Nalorphine	10,000
Normorphine	12,500
Norcodeine	1,500
Oxycodone	25,000
Oxymorphone	25,000
Thebaine	1,500
OPIATE (OPI 50)	
Morphine	50
Bilirubin	3,500
Codeine	10
Diacetylmorphine (Heroin)	50
Ethylmorphine	24
Hydrocodone	100
Hydromorphone	100
Levorphanol	400
6-Monoacetylmorphine	25
Morphine 3-β-D-Glucuronide	50
Nalorphine	10,000
Normorphine	12,500
Norcodeine	1,500
Oxycodone	25,000
Oxymorphone	25,000
Thebaine	1,500
BENZODIAZEPINES (BZO 30)	
α-Hydroxyalprazolam	756
Alprazolam	24
Bromazepam	240
Chlordiazepoxide	468
Chlordiazepoxide HCl	234
Clobazam	60
Clonazepam	471
Clorazepate Dipotassium	117
Delorazepam	936
Desalkylflurazepam	234
Diazepam	117
Estazolam	1,500
Flunitrazepam	231
(±) Lorazepam	936
RS-Lorazepam Glucuronide	96
Midazolam	7,500
Nitrazepam	57
Norchlordiazepoxide	120
Nordiazepam	234
Oxazepam	30
Temazepam	12
Triazolam	1,500

BENZODIAZEPINES (BZO 50)	
α-Hydroxyalprazolam	1,260
Alprazolam	40
Bromazepam	400
Chlordiazepoxide	780
Chlordiazepoxide HCl	390
Clobazam	100
Clonazepam	785
Clorazepate Dipotassium	195
Delorazepam	1,560
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	385
(±) Lorazepam	1,560
RS-Lorazepam Glucuronide	160
Midazolam	12,500
Nitrazepam	95
Norchlordiazepoxide	200
Nordiazepam	390
Oxazepam	50
Temazepam	20
Triazolam	2,500
OXYCODONE (OXY)	
Oxycodone	50
Codeine	25,000
Dihydrocodeine	6,250
Ethylmorphine	12,500
Hydrocodone	1,000
Hydromorphone	6,250
Oxymorphone	1,000
Thebaine	25,000
MARIJUANA (THC 25)	
11-nor-Δ ⁹ -THC-9-COOH	12
Cannabinol	2,000
Δ ⁸ -THC	25
Δ ⁹ -THC	25
MARIJUANA (THC 40)	
11-nor-Δ ⁹ -THC-9-COOH	12
Cannabinol	2,000
Δ ⁸ -THC	40
Δ ⁹ -THC	40
MARIJUANA (THC 50)	
11-nor-Δ ⁹ -THC-9-COOH	12
Cannabinol	2,000
Δ ⁸ -THC	50
Δ ⁹ -THC	50
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000
METHADONE (MTD)	
Methadone	75
Doxylamine	12,500
BARBITURATES (BAR)	
Alphenal	150
Amobarbital	300
Aprobarbital	200
Butobarbital	75
Butalbital	300
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
Secobarbital	1,500

BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine 3-D-Glucuronide	15
Norbuprenorphine 3-D-Glucuronide	200
COTININE (COT)	
(-)-Cotinine	30
S(-)-Nicotine	6,250
L-Glutathione Reduced	40,000
METHYLENEDIPOXYMETHAMPHETAMINE (MDMA)	
(±)-3,4-Methylenedioxyamphetamine	50
Dobutamine Hydrochloride	60,000
p-Hydroxymethamphetamine	15,000
(+)-3,4-Methylenedioxyamphetamine (MDA)	1,500
SYNTHETIC CANNABINOID (K2 20)	
JWH-018 5-Pentanoic Acid Metabolite	20
JWH-073 4-Butanoic Acid Metabolite	20
MAM2201 N-Pentanoic Acid Metabolite	200
JWH-398 N-Pentanoic Acid Metabolite	400
JWH-210 N-(5-Carboxypentyl) Metabolite	2,500
JWH-073 3-Hydroxybutyl Metabolite	2,500
JWH-018 N-4-Hydroxypentyl	8,000
JWH-073 4-Hydroxybutyl Metabolite	40,000
JWH-019 5-Hydroxyhexyl Metabolite	40,000
JWH-018 5-Hydroxypentyl Metabolite	45,000
JWH-122 5-Hydroxypentyl Metabolite	50,000
JWH-122 4-Hydroxypentyl Metabolite	50,000
JWH-019 6-Hydroxyhexyl Metabolite	50,000
RCS-4 N-(5-Carboxypentyl) Metabolite	50,000
Trifluoperazine Dihydrochloride	50,000
Trifluoperazine Hydrochloride	70,000
2,4,6-Trimethylbenzamide	100,000
SYNTHETIC CANNABINOID (K2 10)	
JWH-018 5-Pentanoic Acid Metabolite	10
JWH-073 4-Butanoic Acid Metabolite	10
MAM2201 N-Pentanoic Acid Metabolite	200
JWH-398 N-Pentanoic Acid Metabolite	400
JWH-210 N-(5-Carboxypentyl) Metabolite	2,500
JWH-073 3-Hydroxybutyl Metabolite	2,500
JWH-018 N-4-Hydroxypentyl	8,000
JWH-073 4-Hydroxybutyl Metabolite	40,000
JWH-019 5-Hydroxyhexyl Metabolite	40,000
JWH-018 5-Hydroxypentyl Metabolite	45,000
JWH-122 5-Hydroxypentyl Metabolite	50,000
JWH-122 4-Hydroxypentyl Metabolite	50,000
JWH-019 6-Hydroxyhexyl Metabolite	50,000
RCS-4 N-(5-Carboxypentyl) Metabolite	50,000
Trifluoperazine Dihydrochloride	50,000
Trifluoperazine Hydrochloride	70,000
2,4,6-Trimethylbenzamide	100,000

INTERFERENCE

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the *Oral Cube® Oral Fluid Drug Screen* when tested with concentrations up to 100 µg/mL.

Amphetamine, Methamphetamine, Cocaine, Opiate, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates and Buprenorphine Non-Cross-Reacting Compounds Are:

*Parent compound only:

Chlorothiazide
DL-Chlorpheniramine
Chlorpromazine
Chloroquine
Chlorothiazide
Norethindrone

Digoxin
L-Ψ-Ephedrine
β-Estradiol
Estrone-3-Sulfate
Ethyl-p-Aminobenzoate
L-(-)-Epinephrine

D-Norpropoxyphene
 Noscapine
 DL-Octopamine
 Creatinine
 Deoxycorticosterone
 Dextromethorphan
 Diclofenac
 Diflunisal
 Digoxin
 Diphenhydramine
 L-ψ-Ephedrine
 β-Estradiol
 Estrone-3-Sulfate
 Ethyl-p-Aminobenzoate
 L-(-)-Epinephrine
 Erythromycin
 Fenoprofen
 Furosemide
 Gentisic Acid
 Hemoglobin
 Hydralazine
 Hydrochlorothiazide
 Hydrocortisone
 o-Hydroxyhippuric Acid
 p-Hydroxytyramine
 Ibuprofen
 Iproniazid
 DL-Isoproterenol
 Isoxsuprine
 Ketamine
 Ketoprofen
 Thioridazine
 DL-Tyrosine
 Tolbutamide
 Triamterene
 Trifluoperazine
 Trimethoprim
 DL-Tryptophan
 Uric Acid
 Verapamil
 Zomepirac

Cotinine Non-Cross-Reacting Compounds Are:

*Parent compound only:
 Acetaminophen
 Acetophenetidin
 N-Acetylprocainamide
 Acetylsalicylic Acid
 Amoxicillin
 Amphetamine Sulfate
 Ampicillin
 L-Ascorbic Acid
 Apomorphine
 Aspartame
 Atropine
 Cholesterol
 Clonidine
 Codeine
 Cortisone
 Benzoyllecgonine
 Benzoic Acid
 Benzphetamine
 Caffeine
 Chloramphenicol
 Chlorothiazide
 Chlorpromazine
 Chloroquine
 Cocaine Hydrochloride
 Norethindrone
 D-Norpropoxyphene
 Noscapine
 DL-Octopamine
 Creatinine
 Dextromethorphan
 Diflunisal
 Erythromycin
 Fenoprofen
 Furosemide
 Gentisic Acid

Hemoglobin
 Heroin
 Hydralazine
 Hydrochlorothiazide
 Hydrocortisone
 buprofen
 soxsuprine
 Ketamine
 Labetalol
 Loperamide
 Methadone
 Methamphetamine
 Meperidine
 Meprobamate
 Methylphenidate
 Morphine
 Nalidixic Acid
 Naloxone
 Naltrexone
 Naproxen
 Niacinamide
 Oxymetazoline
 Papaverine
 Penicillin-G
 Perphenazine
 Phencyclidine
 Phenelzine Hydrochloride
 Bromazepam
 Bromocriptine Mesylate Tablets
 Bupivacaine Hydrochloride
 Buprenorphine
 Buspirone Hydrochloride
 Butacaine
 Butalbital
 Butabarbital
 Butyrophenone
 Butethal
 Cannabidiol
 Caffeine
 Sulfamethazine
 Labetalol
 Loperamide
 Meperidine
 Methylphenidate
 Nalidixic Acid
 Naloxone
 Naltrexone
 Naproxen
 Niacinamide
 Nifedipine
 Oxalic Acid
 Oxolinic Acid
 Oxymetazoline
 Papaverine
 Penicillin-G
 Pentazocine Hydrochloride
 Perphenazine
 Phenelzine
 Trans-2-Phenylcyclopropylamine Hydrochloride
 Phenylpropanolamine
 Prednisolone
 Prednisone
 DL-Propranolol
 D-Propoxyphene
 D-Pseudoephedrine
 Quinacrine
 Quinine
 Ranitidine
 Berberine Hydrochloride Tablets
 Benzilic Acid
 Serotonin
 Sulfamethazine
 Sulindac
 Tetracycline
 Tetrahydrocortisone 3-Acetate
 Tetrahydrocortisone 3 (β-D-Glucuronide)
 Thiamine
 Phenylpropanolamine
 Prednisolone
 Prednisone

DL-Propranolol
 D-Propoxyphene
 D-Pseudoephedrine
 Butalbital
 Quinacrine
 Quinine
 Oxycodone
 Ranitidine
 Cannabidiol
 Secobarbital
 Salicylic Acid
 Serotonin
 Sulindac
 Tetracycline
 Thiamine
 Thioridazine
 DL-Tyrosine
 Tolbutamide
 Trifluoperazine
 Trimethoprim
 DL-Tryptophan
 Tyramine
 Uric Acid
 Verapamil
 Zomepirac

Synthetic Cannabinoid Non-Cross-Reacting Compounds Are:
 *Parent compound only:

Acebutolol Hydrochloride
 Acepromazine-d6 Hydrochloride
 Acetylcysteine Effervescent Tablets
 Acetaminophen
 o6-AcetylMorphine
 Acetazolamide Tablets
 N-Acetylprocainamide
 Acetone
 Acetophenetidin
 Alprenolol Hydrochloride
 Alprazolam
 Allopurinol Tablets
 Alphenal
 Amiloride Hydrochloride Tablets
 Amiodarone Hydrochloride Tablets
 Amoxicillin Capsule
 Ampicillin Caps (Ampicinine)
 Amitriptyline Hydrochloride Tablets
 Aminophylline Tablets
 Amantadine Hydrochloride Tablets
 Amphoterin B
 Ammonium Chloride
 Amobarbital
 Amphetamine Sulfate
 Amikacin Hydrate
 Amikacin Sulfate Injection
 4-Aminobenzoic Acid
 DL-Aminoglutethimide
 Aniline Hydrochloride
 Antipyrine
 Aprobarbital
 Aspartame
 L-Ascorbic Acid
 L-Aspartic Acid
 D-Aspartic Acid
 DL-Aspartic Acid
 Atropine Sulfate Injection
 Baclofen Tablets
 Benzphetamine
 Barbituric Acid
 Betamethasone Injection
 Berberine Hydrochloride Tablets
 Benzilic Acid
 Benzocaine
 Benzyl Alcohol
 Benzoyllecgonine
 Bendroflumethiazide
 Benzylamine Hydrochloride
 Benzoic Acid
 Bisacodyl
 Bromazepam
 Bromocriptine Mesylate Tablets
 Bupivacaine Hydrochloride

Buprenorphine
 Buspirone Hydrochloride
 Butacaine
 Butalbital
 Butabarbital
 Butyrophenone
 Butethal
 Cannabidiol
 Caffeine
 Carbamazepine Tablets
 Carisoprodol
 Cefaclor
 Cefradine Capsules
 Ceftriaxone Sodium for Injection
 Cefotaxime Sodium for Injection
 Cefoxitin
 Cefadroxil Capsule
 Cephadrine
 Chlordiazepoxide HCL
 Chloroquine Phosphate
 Chlorpheniramine Maleate Tablets
 Chlorpromazine Hydrochloride Tablets
 Chlorpropamide
 Chlorprothixene Hydrochloride
 Chlorthalidone
 Chlorzoxazone Tablets
 Cimetidine (Tablets)
 (-)-Cinchonidine
 Cinoxacin
 Ciclosporin Soft Capsule
 Citric Acid
 Clenbuterol Hydrochloride
 Clindamycin
 Clobetasone Butyrate
 Clomipramine Hydrochloride Tablets
 Clorazepate Dipotassium
 Kanamycin Sulfate
 2,4,6-Trimethylbezamide
 Triflupromazine Hydrochloride

Methylenedioxyamphetamine Non-Cross-Reacting Compounds are:
 *Parent compound only:

Acebutolol Hydrochloride
 Acetopromazine-d6 Hydrochloride
 Acetylcysteine
 Acetylsalicylic Acid (Aspirin)
 Acetaminophen
 o6-AcetylMorphine
 Acetazolamide
 N-Acetylprocainamide
 Acetone
 Acetophenetidin
 Alprenolol Hydrochloride
 Alprazolam
 Allopurinol
 Alphenal
 Amiloride Hydrochloride
 Aminophenazone (4-Dimethylaminoantipyrine)
 Amiodarone Hydrochloride
 Amoxicillin
 Ampicillin (Ampicinine)
 Amitriptyline Hydrochloride
 Aminophylline
 Amantadine Hydrochloride
 Amphoterin B
 Ammonium
 Amobarbital
 Amikacin Hydrate
 Amikacin Sulfate
 4-Aminobenzoic Acid
 DL-Aminoglutethimide
 Kanamycin Sulfate
 Aniline Hydrochloride
 Antipyrine
 R-(-)-Apomorphine Hydrochloride Hemihydrate
 Aprobarbital
 Aspartame
 L-Ascorbic Acid
 Dimethyl Isosorbide

(Isosorbide Dimethyl Ether)
 Diazepam
 Diflorasone Diacetate
 Digoxin
 Diazoxide
 Dieltrin
 Dipyrone
 Dimethyl Sulfoxide
 5,5-Diphenylhydantoin
 DL-3,4-Dihydroxymandelic Acid
 Benzocaine
 Benzyl Alcohol
 Benzoyllecgonine
 Bendroflumethiazide
 Benzylamine Hydrochloride
 Benzoic Acid
 Bisacodyl
 Bromazepam
 Bromocriptine Mesylate
 Bupivacaine Hydrochloride
 Buprenorphine
 Buspirone Hydrochloride
 Butacaine
 Butalbital
 Butabarbital
 Buprenorphine-3-β-D-Glucuronide
 Butyrophenone
 Butethal
 Cannabidiol
 Caffeine
 Carbamazepine
 Carisoprodol
 Cefaclor
 Cefradine
 Ceftriaxone Sodium
 Cefotaxime Sodium
 Cefoxitin
 Cefuroxime Axetil (Zinnat)
 Cefadroxil
 Cephadrine
 Chlordiazepoxide HCL
 Chloroquine Phosphate
 Chlorpheniramine Maleate
 Chlorpromazine Hydrochloride
 Chlorpropamide
 Chlorprothixene Hydrochloride
 Chlorzoxazone
 Cimetidine (Trichloroacetaldehyde Hydrate)
 Cinmetidine
 (-)-Cinchonidine
 Cinoxacin
 Cyclosporine
 Citric Acid
 Clenbuterol Hydrochloride
 Clindamycin
 Clobetasone Butyrate
 Clomipramine Hydrochloride
 Clorazepate Dipotassium
 Clonazepam
 Clobazam
 Cloxacillin
 Colchicine
 Cholesterol
 (-)-Cotinine
 Cocaehtylene
 Cocaine Hydrochloride
 Codeine
 Creatinine
 Cyclobenzaprine Hydrochloride
 Cyclophosphamide

L-Cystine
 Cyproheptadine Hydrochloride
 Cyclopentobarbital
 Dantrolene Sodium Salt
 Dextromethorphan Hydrobromide
 Dexamethasone Acetate
 Deoxyepinephrine
 Deferoxamine Mesylate
 Desipramine Hydrochloride
 Dihydralazine
 Hemoglobin
 Disopyramide
 Dopamine Hydrochloride
 Doxepin Hydrochloride
 Doxycycline Hydate
 Doxylamine Succinate Salt
 Droperidol
 Ecgonine Methyl Ester
 (±)-Ephedrine Hydrochloride
 Erythromycin Enteric
 Eserine
 Estazolam
 β-Estradiol
 Estriol
 Estrone
 Estrone-3-Sulfate Potassium Salt
 Etoposide
 Ethacrynic Acid
 Ethambutol Hydrochloride
 Ethyl-p-Aminobenzoate
 Ethylenediaminetetraacetic Acid
 Etodolac
 Ethyl Morphine
 Famotidine
 Fenfluramine
 Ferrous(II) Sulfate Heptahydrate
 Fenoprofen Calcium Salt Hydrate
 Flufenamic Acid
 Flunitrazepam
 Flunisolide
 Flurandrenolide
 Flurazepam Dihydrochloride
 Furosemide
 Gemfibrozil
 Gentamicin Sulfate Granules
 Gentisic Acid
 Glutathione Reduced
 Glybenclamide
 Glucose
 Griseofulvin
 Halcinonide
 Heroin Hydrochloride
 Hexachlorophene
 Hypnovel (Cyclobarbital)
 Hippuric Acid
 Histamine
 Hydralazine Hydrochloride
 (1R,9S)-(-)-β-Hydrastine
 Hydroflumethiazide
 Hydromorphone
 Hydrocodone
 Hydroxocobalamin Hydrochloride
 α-Hydroxyhippuric Acid
 Hydroxyzine Dihydrochloride
 α-Hydroxyalprazolam
 17α-Hydroxyprogesterone
 Hydrocortisone
 Hydrochlorothiazide
 Hypoxanthine
 Triamcinolone Acetonide Ointment
 Zinc Undecylenate

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Effective date: 03/11/2022